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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,750	03/22/2005	In-San Kim	428.1050	8168
20311	7590	02/07/2007		
LUCAS & MERCANTI, LLP 475 PARK AVENUE SOUTH 15TH FLOOR NEW YORK, NY 10016			EXAMINER ARNOLD, ERNST V	
			ART UNIT	PAPER NUMBER
			1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/528,750

Applicant(s)

KIM ET AL.

Examiner

Ernst V. Arnold

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 8 and 11-18 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 8 and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 5, 8, and 11-18 are pending in the application.

Applicant's response filed on 10/26/06 has been carefully considered by the Examiner. Newly submitted claims 16-18 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Group I claims 1, 5, 8 and 11-15 are drawn to a composition for stimulating bone-formation and bone-consolidation and Group II claims 16-18 are drawn to a method for stimulating bone-formation and bone-consolidation.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process can use bone morphogenic protein or TGF-beta or FGF or IGF-1 or PDGF rather than beta ig-h3.

Because these inventions are independent or distinct for the reasons given above and there would be an undue burden on the Examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-18 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicants amendments have necessitated a new grounds of rejection. Applicant has amended claims 1 and 8 and introduced new limitations that were not previously presented in claims 11-15 thus requiring further search and consideration by the Examiner. Accordingly, this Action is FINAL.

Claims 1, 5, 8 and 11-15 are under examination.

Withdrawn rejections:

Claims 1-3 were rejected under 35 U.S.C. 102(b) as being anticipated by Hansson et al. (WO 96/02259). Applicant has amended the claims and the Examiner withdraws the rejection.

Claims 1, 2, and 4 were rejected under 35 U.S.C. 102(b) as being anticipated by Shu et al. (International Journal of Pharmaceutics 2000, 201, 51-58). Applicant has amended the claims and the Examiner withdraws the rejection.

Claims 1-10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hansson et al. (WO 96/02259) in view of Kim et al. (Journal of Cellular Biochemistry 2000, 77, 169-178) and Shu et al. (International Journal of Pharmaceutics 2000, 201, 51-58) and Santos et al. (US 5,955,096) and Wilson et al. (Development 1997, 124,

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3177-3184). Applicant has amended the claims and the Examiner withdraws the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 introduces new matter as the claims recites the limitation "...100 µg/ml ~ 1 mg/ml". There is no support in the specification or the claims for this range. The limitation of "...100 µg/ml ~ 1 mg/ml" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. There is no guidance in the specification, in the text or in the examples, to select the upper range value of 1 mg/ml. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 5, 8, and 11-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al. (Plastic and Reconstructive Surgery 2002 (May), 109(6), 1966-1977).

Kim et al. disclose a dual syringe needle containing 0.5 cc of 450 µg/ml βig-h3 dissolved in 5% chitosan solution in one chamber and 0.5 cc of 5% tripolyphosphate in the other chamber which was injected into the distracted zone of a dog (Page 1968, left column and Figure 2). Kim et al. disclose that injection results in the mixing of the two solutions which then hardened (Page 1968, left column). It is the Examiner's position that the hardened material disclosed by Kim et al. meets the limitations of instant claims 1, 5, 8, and 11-15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5, 8, and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (J Korean Soc Plast Reconstr Surg 2001, 28(3), 223-232).

Applicant claims a composition for stimulating bone-formation and bone-consolidation comprising a water-soluble chitosan, a tripolyphosphate, and β ig-h3 protein, wherein a mixed ratio of the tripolyphosphate to the water-soluble chitosan is 20:80 ~ 80:20 weight %, and wherein the β ig-h3 protein is contained in the water-soluble chitosan at a concentration of 100 μ g/ml ~ 1 mg/ml.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Kim et al. (J Korean Soc Plast Reconstr Surg 2001, 28(3), 223-232) teaches the effect of chitosan, 450 μ g/ml β ig-h3 and human bone morphogenic protein-4 on early bone consolidation (Abstract and page 225, right column). Kim et al. teach the use of a dual syringe to inject 0.5 cc of each bone growth material and 0.5 cc of 5%

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tripolyphosphate into the distracted zone for solidification of the injected solution (Abstract and page 225, Figure 1).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Kim et al. do not expressly teach a composition for stimulating bone-formation and bone-consolidation comprising a water-soluble chitosan, a tripolyphosphate, and β ig-h3 protein, wherein a mixed ratio of the tripolyphosphate to the water-soluble chitosan is 20:80 ~ 80:20 weight %, and wherein the β ig-h3 protein is contained in the water-soluble chitosan at a concentration of 100 μ g/ml ~ 1 mg/ml.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust the composition of Kim et al. to have a water-soluble chitosan, a tripolyphosphate, and β ig-h3 protein, wherein a mixed ratio of the tripolyphosphate to the water-soluble chitosan is 20:80 ~ 80:20 weight %, and wherein the β ig-h3 protein is contained in the water-soluble chitosan at a concentration of 100 μ g/ml ~ 1 mg/ml and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Kim et al. teach that chitosan and β ig-h3 protein can be used for the same purpose and it is obvious to combine components used for the same purpose. "It is prima facie obvious to

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combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

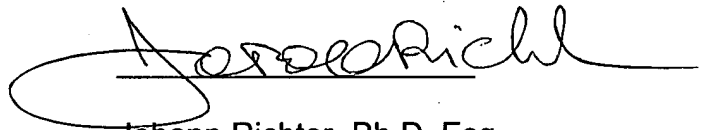
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
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A handwritten signature in black ink, appearing to read "Johann Richter", with a large, stylized loop at the beginning.

Johann Richter, Ph.D. Esq.
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